Remarks

Claims 1, 4-9, and 11-13 were previously pending in the subject application. By this Amendment, claims 1, 9, 12 and 13 have been amended and claim 7 has been canceled. No new matter has been added by these amendments. Specifically, support for the use of the terms "intact single dosage" (see page 3, line 6) and "for oral or buccal administration" (see page 3, line 36) can be found in the specification. Accordingly, claims 1, 4-9, and 11-13 are now before the Examiner for consideration.

The amendments to the claims have been made in an effort to lend greater clarity to the claimed subject matter and to expedite prosecution. The amendments should not be taken to indicate the applicants' agreement with, or acquiescence to, the rejections of record. Favorable consideration of the claims now presented, in view of the remarks and amendments set forth herein, is earnestly solicited.

Claims 1, 7, 9, and 11-13 have been rejected under 35 U.S.C. §102(b) as being anticipated by Koyama *et al.* (U.S. Patent No. 4,824,938). The applicants respectfully traverse this ground of rejection because the cited reference does not teach each and every element of the claimed composition.

Koyama *et al.* teach a water-soluble composition comprising pullulan and a bioactive substance. The composition is freeze-dried in a glass vial (see examples 1 and 2). Koyama *et al.* do not, however, state that the composition is an intact single dosage, as required by the claims as amended. In fact, Koyama *et al.* disclose that the product composition is useful as a test reagent or for intravenous or intramuscular injection (see examples 1 and 2 – col. 6, lines 51-53 and 66-68). This implies that the product composition will need to be converted into liquid form before being administered. Thus, the compound taught by Koyama *et al.* is clearly not an intact single dosage and, thus, is distinguishable from the claimed composition.

Additionally, Koyama *et al.* do not teach a composition for oral or buccal administration comprising pullulan. As noted above, the product composition containing pullulan is contemplated only for use as a test reagent or for injection. On the other hand, it is an advantage of the claimed composition that it is for oral or buccal administration. Therefore, Koyama's composition is plainly different than the current invention.

Furthermore, the Examiner indicates that Koyama *et al.* meet the claim limitation of a shaped body since the composition is freeze-dried in a glass vial. However, freeze-drying in a glass vial will not necessarily form a shaped body in the shape of the vial. Depending on the positioning of the frozen water that sublimes during the freeze-drying process and the arrangement of the solution when it is first frozen, the resulting composition could potentially take an abstract shape. Therefore, the composition of Koyama *et al.* does not meet the requirement of the claimed composition that it be a shaped body.

It is well established that in order to anticipate, a single reference must disclose within the four corners of the document each and every element and limitation contained in the rejected claim. *Scripps Clinic & Research Foundation v. Genentech Inc.*, 18 U.S.P.Q.2d 1001, 1010 (Fed. Cir. 1991). As discussed above, Koyama *et al.* do not teach a composition for oral or buccal administration that is an intact single dosage. Koyama *et al.* also fail to disclose a composition in the form of a shaped body. Accordingly, the applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. §102(b) based on the Koyama reference.

Claims 1, 7, 9, and 11-13 have been rejected under 35 U.S.C. §102(b) as being anticipated by JP 53012417 (hereinafter referred to as JP). The applicants respectfully traverse this ground of rejection because the cited reference does not teach each and every element of the claimed composition.

JP teaches the preparation of submorphous drugs by adding pullulan to aqueous drug solutions and freeze-drying them. However, JP does not teach that its composition is an intact single dosage. Rather, JP discloses how the submorphous drugs are prepared, without any reference to whether the listed steps are complete or how the product of the listed steps would be used. Thus, the composition of JP is clearly distinguishable from the present invention.

Furthermore, JP fails to teach that its composition is for oral or buccal administration. JP does disclose that the product dissolves more rapidly in gastric juices, but does not explicitly state that the composition is for oral or buccal administration. JP is very ambiguous on how the drugs should be administered, and oral or buccal administration, as in the claimed invention, is not clearly taught.

Additionally, as the Examiner points out, JP does not explicitly mention a shaped body as required by the claims. The Examiner states that the freeze-drying process can only be done in a vial and that this meets the shaped body requirement. As discussed above with regard to the Koyama patent, freeze-drying in a glass vial will not necessarily produce a shaped body. Moreover, the freeze-drying process need not be done in a rigidly-shaped vial. It could potentially be carried out in any container, of any shape, that can hold the solution as it is freeze-dried. Therefore, JP does not disclose a composition in the form of a shaped body, as required by the claimed composition.

As discussed above, in order to anticipate, a single reference must disclose within the four corners of the document each and every element and limitation contained in the rejected claim. *Scripps Clinic & Research Foundation v. Genentech Inc.*, 18 U.S.P.Q.2d 1001, 1010 (Fed. Cir. 1991). The JP reference does not teach each and every element of the claimed composition. Accordingly, the applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. §102(b) based on JP.

Claims 4-6 and 8 have been rejected under 35 U.S.C. §103(a) as being obvious over Koyama *et al.* (U.S. Patent No. 4,824,938). The applicants respectfully traverse this ground of rejection because the cited reference does not teach or suggest the claimed composition.

Many of the differences between the composition taught by Koyama *et al.* and the current invention have been discussed above. In addition, the additives suggested by Koyama *et al.* are quite different than the excipients of the instant claims. Koyama *et al.* give an extensive list of substances that can be added, but fail to mention those recited by the claimed invention. There is no suggestion anywhere in the Koyama reference to use the excipients in the claimed composition.

Also, the internal or external treatment and tablets contemplated by Koyama *et al.* are for compositions that do not include pullulan (see col. 6, lines 31-33, col. 8, lines 13-17). The compositions taught by Koyama *et al.* that do include pullulan are for injection or for test reagents (see examples 1 and 2 – col. 6, lines 51-53 and 66-68). One skilled in the art would not expect a composition used for injection to necessarily be useful in another form of

administration. Thus, there is no motivation or expectation of success for combining the different aspects of the Koyama reference to arrive at the compositions in the currently rejected claims.

It has been well established in the patent law that the mere fact that the purported prior art could have been modified or applied in some manner to yield applicant's invention does not make the modification or application obvious unless the prior art suggested the desirability of the modification. *In re Gordon*, 221 USPQ 1125,1127 (Fed. Cir. 1984). Moreover, as expressed by the CAFC, to support a §103 rejection, "[b]oth the suggestion and the expectation of success must be founded in the prior art ..." *In re Dow Chemical Co.* 5 USPQ 2d 1529, 1531 (Fed. Cir. 1988). An assertion of obviousness without the required suggestion or expectation of success in the prior art is tantamount to using applicant's disclosure to reconstruct the prior art to arrive at the subject invention. Hindsight reconstruction of the prior art cannot support a §103 rejection, as was specifically recognized by the CCPA in *In re Sponnoble*, 56CCPA 823, 160 USPQ 237, 243 (1969).

Since there is no suggestion to combine the different parts of the Koyama reference, the claimed composition would not have been obvious to one of ordinary skill in the art. Accordingly, the applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. §103(a) based on Koyama *et al.*

In view of the foregoing remarks, the applicant believes that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

The applicant also invites the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephone interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,

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